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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,481	11/10/2003	Sonya S. Johnson	112703-306	5154
29156 K&L Gates LLI	7590 03/05/201 <b>P</b>	EXAMINER		
P.O. Box 1135	60600	ROBERTS, LEZAH		
CHICAGO, IL 60690			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			03/05/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

		Application No.	Applicant(s)		
Office Action Summary		10/705,481	JOHNSON ET AL.		
		Examiner	Art Unit		
		LEZAH W. ROBERTS	1612		
 Period for	The MAILING DATE of this communication app Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ 5	Responsive to communication(s) filed on <u>03 No</u>	ovember 2009			
'=	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.				
/—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
-	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
J		n panto dadyro, 1000 0.2. 11, 10	0 0.0.210.		
Dispositio	n of Claims				
<ul> <li>4)  Claim(s) 1,4,7-11,14,18-21 and 24-33 is/are pending in the application.</li> <li>4a) Of the above claim(s) 21 and 24-26 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1, 4, 7-11, 14, 18-21 and 27-33 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9) <u></u> ⊤I	ne specification is objected to by the Examinei	r.			
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
А	pplicant may not request that any objection to the o	drawing(s) be held in abeyance. See	37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority un	der 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
2)  Notice (3) Informa	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) tion Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	te		

#### **DETAILED ACTION**

Applicants' arguments, filed November 3, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

# Specification

The amendment filed November 3, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The deleted material which is not supported by the original disclosure is as follows: the specification discloses "In an embodiment, a chewing gum comprising Erospicata oil and cooling agent selected from the group consisting of menthol, menthol glyceryl ether, N,2,3-trimethyl-2-isopropyl-butamide and menthyl glutamate or combinations thereof".

Although Applicant has deleted this paragraph in order to clarify the definition of "cooling agent", which is defined as non-menthol cooling agents, yet Applicant has not only deleted the menthol cooling agents but also those that are not encompassed by menthol and therefore it appears the deletion of N,2,3-trimethyl-2-isopropyl-butamide

and menthyl glutamate, which appear to be non-menthol cooling agents, appears to be "New Matter".

Applicant is required to cancel the new matter in the reply to this Office Action.

#### **Claims**

### Claim Rejections - 35 USC § 112 - Written Description (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation wherein the menthol comprises at least 0.02% by weight". The specification does not appear to support this limitation because the recitation of "at least" supports amounts various amounts greater than 0.02 and the specification only appears to support menthol with a concentration of 0.02%, 0.03% and 0.1 to 20% in the case of edible film formulations. Thus, the limitation appears to be "New Matter".

### Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (US 5,009,893) in view of Oppenheimer et al. (US 4,980,169) and Sturtz (US Plant 8,645).

Cherukuri et al. disclose edible compositions capable of providing long-lasting, breath freshening perception without bitterness which comprises using a cooling agent comprising menthol and an N-substituted-p-methane carboxamide compound (Abstract). Menthol comprises 5 to 70% by weight of the cooling composition and the N-substituted-p-methane carboxamide compound comprises 30 to 95% of the cooling composition. The cooling composition comprises 0.01 to about 2.0% of the product composition (col. 4, lines 17-38). The cooling compositions may be added to chewing gums (col. 5, lines 30-35). Flavor oils may be added to the compositions (col. 6, lines 18-20). Peppermint comprises 1.1438% of the composition (Table 1).

The reference differs from the instant claims insofar as it does not disclose one of the warming agents recited in the instant claims or that the compositions comprise erospicata oil.

Oppenheimer et al. disclose confections containing a volatile oil. The compositions contains a sensorially undetectable amount of a volatile oil modifying agent which enhances the flavor of the volatile oil as well as ameliorates the perception of unpleasant organoleptic sensation such as bitterness initiated by the volatile oil being released in the oral cavity. The modifying agent is preferably the oleoresin form of capsicum (see Abstract). The compositions comprise both menthol and eucalyptus,

which is also a cooling agent, as the volatile oil components (col. 4, lines 14-20). Other volatile oil components include peppermint oil and extracts derived from other plants (col. 6, lines 10-20). The volatile oil comprises 0.05 to about 1.0% by weight of the confection (see claim 5). Other additives such as flavors, colorants and the like may also be added to the compositions (col. 4, lines 51-53). Additional flavors include natural and artificial flavors such as peppermint and various fruit flavors (col. 6, lines 59-65). The modifying agent may comprise 1 to 150 parts per million by weight of the product (col. 3, lines 10-16), which translates to 0.0001 to 0.015%, encompassing claim 4.

The reference differs from the instant claims insofar as it does not disclose erospicata oil in the recited amount is present in the compositions or that the composition is a chewing gum.

It would have been obvious to one of ordinary skill in the art to have used a warming agent such as capsicum oleoresin in the compositions of Cherukuri et al. motivated by the desire to insure the perception of unpleasant organoleptic sensation such as bitterness was ameliorated as well as enhance the flavor of the cooling agents, as disclosed by Oppenheimer et al.

The combination of Cherukuri et al. and Oppenheimer et al. differs from the instant claims insofar as it does not disclose using erospicata oil in the compositions.

Sturtz teaches a new mint plant species named Erospicata and has the same organoleptic properties as peppermint oil (col. 2, lines 21-23). The reference teaches Erospicata has a characteristic peppermint taste and smell, yet its oil contains much

lower levels of menthol and much higher levels of menthone, less than 1%. The low menthol content of the essential oil is important because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium, therefore only very small amounts of conventional peppermint oil can be added to ingestible products such as candy. The menthone content provides a "hot" peppermint taste and odor. The absence of this alcohol helps avoid nasal and gastrointestinal irritation, while the menthone provides peppermint-like organoleptic properties. The mint plant also expresses an oil that is low in carvone and piperitone content. The substantial absence of carvone and piperitone is important because these substances provide a taste that is organoleptically undesirable in peppermint oil. Carvone provides a spearmint taste, while piperitone imparts a bitter taste (col. 2, lines 5-36).

The reference differs from the instant claims insofar as it does not teach consumable products such as chewing gums comprising a cooling agent, a heating agent or a method of enhancing the flavor of an oral product by adding Erospicata and a cooling agent or heating agent.

It would have been obvious to one of ordinary skill in the art to have used erospicata as a flavor in place of or in addition to peppermint in the disclosed amount of 1.1438 in the compositions of Cherukuri et al. in view of Oppenheimer et al. motivated by the desire to use a flavor that will give the composition the taste of peppermint oil without adding additional menthol that would lead to irritation or would lead to a bitter taste due to the additional menthol as disclosed by Sturtz.

In regards to claims 27-31, when Erospicata is added to the consumable compositions, it may be added in higher amounts to enhance or add more peppermint flavor without the effects of menthol. In regards to the claims 32-33, it would have been obvious to reduce the amount of peppermint originally used in the gum composition because the addition of erospicata can provide similar effects, e.g., flavor and organoleptic effects, without the irritation of extra menthol.

In regard to the amount of warming agent in claim 4, the prior art does not disclose the exact claimed values 0.1% to about 2.0%, but does overlap, 0.0001% to 0.015%: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. <u>In re Peterson</u>, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected.

Claims 21 and 24-26 are withdrawn.

No claims allowed.

## Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/ Examiner, Art Unit 1612

/Frederick Krass/ Supervisory Patent Examiner, Art Unit 1612